IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
THIS DOCUMENT RELATES TO:	)	
SHEILA BROWN, et al. v. AMERICAN HOME PRODUCTS CORPORATION	)	CIVIL ACTION NO. 99-20593 2:16 MD 1203

MEMORANDUM AND PRETRIAL ORDER NO. _____

Bartle, C.J. June 12, 2007

Debbie LeBoon ("Ms. LeBoon" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,[1] seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").[2]

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did

(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. Part I of the Green Form is to be completed by the claimant or the claimant's representative. Part II is to be completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, Part III is to be completed by the claimant's attorney if he or she is represented.

In May 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician Michael Liston, M.D. Dr. Liston is no stranger to this litigation. See, e.g., Pretrial Order ("PTO") No. 6339 at 3 (May 24, 2006). Based on an echocardiogram dated October 19, 2001, Dr. Liston attested in Part II of Ms. LeBoon's Green Form that she suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and an ejection fraction in the range of 50% to 60%. Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of $497,928.

2(...continued)
not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period, or who took the drugs for 60 days or less, or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

In the report of claimant's echocardiogram, Dr. Liston stated that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 24%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Liston also stated that claimant had mild to moderate left atrial enlargement and her left atrium measured 4.8 cm in the parasternal view. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b). Finally, Dr. Liston indicated that claimant's ejection fraction was 60%. An ejection fraction is considered reduced for purposes of a mitral valve claim if it is measured as less than or equal to 60%. See id.

In September, 2002, the Trust forwarded the claim for review by Keith B. Churchwell, M.D., one of its auditing cardiologists. In audit, Dr. Churchwell concluded that there was no reasonable medical basis for Dr. Liston's finding that claimant had moderate mitral regurgitation because her echocardiogram demonstrated only mild mitral regurgitation. More specifically, Dr. Churchwell stated that "[o]verestimation of area of regurgitation jet is seen - small jet approximately

moderately dilated atrium < 20% of LA area." Dr. Churchwell, however, determined that there was a reasonable medical basis for concluding that claimant's left atrial dimension was abnormal. Dr. Churchwell was not asked to review claimant's ejection fraction.[3]

Based on Dr. Churchwell's finding of mild mitral regurgitation, the Trust issued a post-audit determination denying Ms. LeBoon's claim. Pursuant to the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures"), claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7; PTO No. 2457 (May 31, 2002), Audit Policies and Procedures § VI.[4] The Trust then applied to the court for issuance of an Order to show cause

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3. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's findings of an abnormal left atrial dimension and a reduced ejection fraction, each of which is one of the complicating factors needed to qualify for a Level II claim, the only issue is claimant's level of mitral regurgitation.

4. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Ms. LeBoon's claim.

why Ms. LeBoon's claim should be paid. On February 6, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2744 (Feb. 6, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served an amended response upon the Special Master. The Trust submitted a reply on June 13, 2003. Under the Audit Policies and Procedures it is within the Special Master's discretion to appoint a Technical Advisor[5] to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by the Trust and claimant, and to prepare a report for the court. The Show Cause Record and Technical Advisor's Report are now before the court for final determination. Id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's finding

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5. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge–helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

that she had moderate mitral regurgitation. See Audit Policies and Procedures § VI.D. Ultimately, if we determine that there was no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must confirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there was a reasonable medical basis, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. LeBoon submitted two expert opinions. First, claimant provided an echocardiogram report from William Gries, M.D., which stated that claimant had an RJA/LAA ratio of 0.227, or 22.7%.[6] Dr. Gries also provided an unverified letter dated March 15, 2003, in which he opined:

> It is my opinion that this echo demonstrates moderate mitral regurgitation by appropriate application of the Singh method. The extent of mitral regurgitation is demonstrated in real time imaging with representative still frame measurements. Multiple measurements were made of the mitral regurgitant jets, which were traced accurately and appropriately.

REGURGITANT JET AREA	RJA/LAA
3.83	0.227
3.59	0.213
3.47	0.206

6. Dr. Gries also stated that claimant's left atrium measured 4.8 cm, and her ejection fraction was 60%.

	Where LAA = 16.87

> As shown above, the three greatest measurements of regurgitant jet area, all fulfill criteria for moderate mitral regurgitation by the Singh method.

Second, claimant provided a May 2, 2003 letter authored by Steven J. Mattleman, M.D., F.A.C.C., along with Dr. Mattleman's curriculum vitae. In the letter, Dr. Mattleman stated that, "with a reasonable degree of medical certainty," claimant's October 19, 2001 echocardiogram showed an RJA/LAA ratio of 22.7%. Dr. Mattleman also included four printouts purportedly showing mitral regurgitant jets occupying "21%, 21.4% and 22% of the left atrium area which is 15.61 cm^2."[7]

Claimant also argues that the term "reasonable medical basis" means that an attesting physician's conclusions must be accepted unless they were "irrational, foolish, senseless, etc. from any medical perspective" and that an opinion lacks a reasonable medical basis only when "it is so slanted as to exist outside of the 'present state of science.'" Finally, claimant

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7. Dr. Mattleman's report also states:

> The opinions rendered in this report are based on a reasonable degree of medical certainty and are intended to provide legal consultation for forensic expert evaluation only. The report is not intended to provide medical opinions regarding treatment of the identified patient. No one should rely on the opinions expressed in this report for the diagnosis, prognosis, or treatment of their medical condition. The interpretation above does not constitute a doctor-patient relationship with the above patient.

argues that the auditing cardiologist did not follow the Settlement Agreement because he visually estimated her level of mitral regurgitation as opposed to taking actual measurements, which, in her view, are required by the Settlement Agreement.

In response to claimant's show cause submissions, the Trust disputes claimant's characterization of the reasonable medical basis standard and contends that Dr. Churchwell properly relied on the standards set forth in the Settlement Agreement.

The Technical Advisor, Dr. Vigilante concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Dr. Vigilante reviewed claimant's echocardiogram and stated in his Report:

> I reviewed the Claimant's echocardiogram in detail. The date of the study was documented as October 19, 2001. However, a "Blue Strip" on the top of the echocardiogram documented the date of October 24, 2001. This was an average quality study. There were three copies of this echocardiogram on the tape.
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> * * *
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> The parasternal long axis view demonstrated only trace mitral regurgitation. The apical two chamber view demonstrated very mild mitral regurgitation with a RJA/LAA less than 10%. The gain of the color flow was also inaccurate as color artifact was seen within the myocardium. Prior to recording of the apical four chamber view in "real-time", several non-representative still frames of supposed mitral regurgitation jet areas were made by the sonographer. In real-time, the mitral regurgitation was only mild in the apical four chamber view. The non-representative frames measured by the sonographer contained non-mitral regurgitant

> jet flow. The real-time images of the apical four chamber view had a RJA/LAA less than 15%.
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> * * *
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> In response to Question 1, there is no reasonable medical basis for the Attesting Physician's answer to Green Form Question C.3.a. That is, only mild mitral regurgitation was noted on the Claimant's echocardiogram of October 19, 2001. Inaccurate RJA measurements were made by the Attesting Cardiologist in non-representative frames of the mitral regurgitation jet. The RJA/LAA was less than 15%. It would not be possible for a reasonable echocardiographer to conclude that any more significant mitral regurgitation than mild was present on this study.

After reviewing the entire Show Cause Record, we find that claimant's arguments regarding her level of mitral regurgitation are without merit. First, and of crucial importance, claimant does not contest the findings of the auditing cardiologist Dr. Churchwell and Technical Advisor Dr. Vigilante. Claimant does not adequately refute or respond to Dr. Churchwell's determination that there was an overestimation of her regurgitant jet. Nor does she challenge the Technical Advisor's conclusions that: (1) the gain of the color flow was inaccurate as color artifact was seen in the myocardium; (2) several non-representative still frames were made by the sonographer and that such frames included non-mitral regurgitant jet flow; and (3) her RJA/LAA ratio, viewed properly in "real-time," was less than 15%. Despite the opportunity to respond to

these specific findings, claimant did not challenge the Technical Advisor's Report.

We also disagree with claimant's definition of reasonable medical basis. Claimant relies on Gallagher v. Latrobe Brewing Co., 31 F.R.D. 36 (W.D. Pa. 1962), and Black's Law Dictionary, 1538 (6th ed. 1990), for determining what constitutes a reasonable medical basis. Such reliance, however, is misplaced. In Gallagher, the court addressed the situation where a court would appoint an impartial expert witness to be presented to the jury. See Gallagher, 31 F.R.D. at 38. Claimant also relies on the definition of "unreasonable" in Black's. One of the definitions, however, is "not guided by reason." The word "unreasonable" does not always mean "irrational" or "capricious" as claimant would have us believe and does not mean that here. We are not persuaded that either Gallagher or Black's supports claimant's position.

Instead, we are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiograms; (3) failing to

examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-15, 22, 26 (Nov. 14, 2002). Here, Dr. Churchwell determined in audit, and Ms. LeBoon does not dispute, that claimant's RJA was overestimated. The Technical Advisor, Dr. Vigilante, confirmed that claimant's RJA was overestimated in several non-representative frames that included non-regurgitant jet flow and that the gain of the color flow was inaccurate as color artifact was seen in the myocardium. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

Finally, we disagree with claimant's arguments concerning the required method for evaluating a claimant's level of valvular regurgitation. Moderate mitral regurgitation is defined as "20%-40% RJA/LAA," which is based on the grading system required by the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Although the Settlement Agreement specifies the percentage of regurgitation needed to qualify as having moderate mitral regurgitation, it does not specify that actual measurements must be made on an echocardiogram to determine the amount of a claimant's regurgitation. As we explained in PTO No. 2640, "'[e]yeballing' the regurgitant jet to

assess severity is well accepted in the world of cardiology." See PTO No. 2640 at 15.

While claimant relies on the Settlement Agreement's use of the word "measured" in the definition of "FDA Positive", its meaning must be considered in the context of the phrase "by an echocardiographic examination", which immediately follows it. See Settlement Agreement § I.22.b. In its entirety, the phrase placed at issue by claimant is "measured by an echocardiographic examination." Under the plain meaning of this phrase, actual measurements for assessing the level of mitral regurgitation are not required. To the contrary, a claimant's level of regurgitation must be determined based on an echocardiogram, as opposed to other diagnostic techniques. Claimant essentially requests that we write into the Settlement Agreement a requirement that actual measurements of mitral regurgitation be made to determine if a claimant qualifies for Matrix Benefits. There is no basis for such a revision and claimant's argument is contrary to the "eyeballing" standards we previously have evaluated and accepted in PTO No. 2640.

For the foregoing reasons, we conclude that claimant has not met her burden in proving that there is a reasonable medical basis to conclude that she had moderate mitral regurgitation. Therefore, we affirm the Trust's denial of her claim for Matrix Benefits.

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PRETRIAL ORDER NO. _____

AND NOW, on this 12th day of June, 2007, for the reasons set forth in the accompanying Memorandum, it is hereby ORDERED that the post-audit determination of the AHP Settlement Trust is AFFIRMED and the Level II Matrix claim submitted by claimant Debbie LeBoon is DENIED.

BY THE COURT:

_____ /s/ Harvey Bartle III
C.J.